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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,620	12/02/2003	John J. O'Mahony	3659-74	2604

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EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/724,620

Applicant(s)

O'MAHONY ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/2/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/26/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of claims 1-32 in the reply filed on 15 December 2005 is acknowledged.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-24 and 26-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 13, 15, 16, and 19-24 of U.S. Patent No. 6,685,664 to Levin in view of US 5,188,593 to Martin. The patented Levin method claims the insertion of a catheter into a patient and the instantly claimed method claims the insertion of a dual-lumen catheter into a patient, along with the other steps and limitations of the claims. The original claim limitation is silent as to whether the catheter is a single or dual-lumen catheter. However, Martin discloses an insertable dual-lumen catheter with sidewall openings for hemodialysis procedures in order to require only one venous access for both withdrawal and return of blood to the patient in an extracorporeal blood treatment procedure (see column 2, lines 46-58). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a dual-lumen catheter as disclosed by Martin in the method claimed by Levin in order to provide a singular vascular access for withdrawal and return of the blood, as taught by Martin.

With regard to claims 10 and 11, the size ranges are not identical between the patented diameter and length and the instantly claimed diameter and length. It has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. See MPEP § 2144.05.

With regard to claims 12 and 13, Martin illustrates a dual-lumen catheter wherein the tip of the withdrawal catheter comprises a lumen with a larger cross-sectional area near the single-lumen tip area and a smaller cross-sectional area near the proximal, dual-lumen area of the catheter (see FIG 3). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP § 2144.05.

With regard to claims 3 and 15-22, Martin illustrates that the return lumen is located upstream of the withdrawal lumen within the patient's vein, resulting in some amount of recirculation of the blood during the treatment procedure. Martin remains silent as to the percentage of recirculation, distance between the withdrawal and return ports, and cross-sectional areas of the lumens and sidewall ports. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP § 2144.05.

4. Claim 25 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,685,664 to Levin in view of US 6,461,321 to Quinn. The patented Levin method claims the insertion of a catheter into a patient and the instantly claimed method claims the insertion of a dual-lumen catheter into a patient, along with the other steps and limitations of the claims. The original claim limitation is silent as to whether the catheter is a single or dual-lumen

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catheter. However, Quinn discloses a dual-lumen indwelling dialysis catheter that uses pumping action (negative pressure to the withdrawal lumen and positive pressure to the return lumen) to move blood through the catheter from the patient to the treatment device and back wherein the structure of the catheter is designed to minimize patient and blood trauma (see column 1, lines 59-64). . Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a dual-lumen catheter and a positive pumping pressure to return treated blood to the patient in the patented method, in order to move blood through the system with a minimal disruption to the patient and the blood, as taught by Quinn.

### ***Conclusion***


5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 6,579,259 Stevens et al
  - i. Method for extracorporeal cardiac bypass
- b. US 5,928,181 Coleman
  - ii. Cardiac bypass with vena cava suction

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
13 February 2006